510(k) Summary

Submission Information

Name and Address of Sponsor: Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401

MAR 2 0 2003

For Information contact: Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401

Device Identification

Proprietary Name: Global Modular Replacement System Adapter

Common Name: Proximal Femoral Replacement

Classification Name and Reference: Prosthesis, Hip, Semi-constrained Metal/Polymer Uncemented

Proposed Regulatory Class: Class II

Device Product Code: OR(87) LWJ

Intended Use

The GMRS Adapter is intended to mate the Proximal Femoral Components and Femoral Bodies of the MRS or Proximal Femoral Body or Extension Pieces of the GMRS to the distal femoral stems of the Restoration™ Modular Hip System. The GMRS adapter is intended for use with the above-noted components in proximal femoral replacement indicated in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of bone is required. Adequate bone stock must be present to allow the use of the Restoration™ Modular Distal Femoral Stems Indications and contraindications of the GMRS Adapter

when used with the Proximal Femoral Bodies of the MRS and GMRS, and the distal femoral stems of the Restoration™ Modular Hip System follow:

Indications

Proximal femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of the bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications.

Contraindications

A. As related to Bone Tumors

Not all bone tumors may be treated successfully by segmental resection. Any condition that may have already resulted in either local or distant spread of the tumor may be a contraindication. Examples of such conditions include:

- pathological fracture;
- overt infection;
- inopportune placement of biopsy incision; and,
- rapid disease progression beyond a respectable margin.

C. As related to Failed Previous Prosthesis and Trauma

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation that cannot provide adequate support and fixation of the prosthesis

For the use of GMRS Adaper with the Distal Stems of the Restoration Modular Hip System, the following additional contraindication should be noted:

- Inadequate bone stock to allow the use of a press fit stem

K023692
page 3 of 3
The GMRS Adapter is intended to be used in a press fit mode.

Device Description

The GMRS Adapter is a single use, two piece design consisting of the Adapter and the Adapter Locking Screw. The GMRS Adapter is fabricated from titanium alloy (titanium -6 Aluminum-4 Vanadium) and is available in four sizes: standard, +10mm, +20mm, and +30mm. The proximal portion of the GMRS Adapter serves as the male portion of a taper lock that is assembled to the female taper in the distal end of the MRS or GMRS Proximal Femoral Component or Extension Pieces. The distal portion of the GMRS Adapter contains a female taper that accepts the male taper of the Restoration™ Modular Distal Femoral Stems. There are scribe marks on the GMRS Adapter to allow the surgeon to orient the amount of anteversion of the MRS or GMRS Proximal Femoral Component. The proximal portion of the male taper of the GMRS Adapter contains a female thread that serves two purposes: 1) to accept the GMRS Adapter Locking Screw after the taper lock has been engaged; and 2) for mating with a separation instrument should the surgeon need to reposition the adapter after it has been assembled to the Distal Stems of the Restoration™ Modular Total Hip System.

The GMRS Adapter Locking Screw is fabricated from titanium alloy (titanium- 6 Aluminum -4 Vanadium) and is available in four sizes that correspond to the sizes of the Adapter: standard; +10mm, +20mm, and +30mm. The GMRS Adapter Locking Screw is used to augment the taper lock of the GMRS Adapter into the Restoration™ Modular Distal Femoral Stems. The GMRS Adapter Locking Screw is packaged with the corresponding size GMRS Adapter.

Equivalent products include:

1. Femoral Body Segments of the MRS System - Howmedica Osteonics Corp.
2. T3 Femoral Component - Howmedica Osteonics Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Ms. Margaret Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17 South
Allendale, NJ 07401

Re: K023692
Trade/Device Name: Global Modular Replacement System (GMRS) Adapter
Regulation Number: 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LWJ
Dated: February 10, 2003
Received: February 12, 2003

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023692 GMRS Adapter
Response to Questions
February 25, 2003

page 1 of 2

510(k) Number (if known): K023692

Device: GMRS Adapter

The GMRS Adapter is intended to mate the Proximal Femoral Components and Femoral Bodies of the MRS or Proximal Femoral Body or Extension Pieces of the GMRS to the distal femoral stems of the Restoration™ Modular Hip System. The GMRS adapter is intended for use with the above-noted components in proximal femoral replacement indicated in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of bone is required. Adequate bone stock must be present to allow the use of the Restoration™ Modular Distal Femoral Stems. Indications and contraindications of the GMRS Adapter when used with the Proximal Femoral Bodies of the MRS and GMRS, and the distal femoral stems of the Restoration™ Modular Hip System follow:

Indications

Proximal femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of the bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications.

Contraindications

A. As related to Bone Tumors

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Division of General, Restorative and Neurological Devices

510(k) Number K023692

B. As related to Failed Previous Prosthesis and Trauma

K023692

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation that cannot provide adequate support and fixation of the prosthesis.

For the use of GMRS Adaper with the Distal Stems of the Restoration Modular Hip System, the following additional contraindication should be noted:

- Inadequate bone stock to allow the use of a press fit stem

The GMRS Adapter is intended to be used in a press fit mode.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

for Mark N Milhan

Division Sign-Off
Division of General, Restorative and Neurological Devices

510(k) Number K023692